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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,682	08/22/2003	Dennis S. Fernandez	FERN-P013	1019
22877 7590 05/14/2008 FERNANDEZ & ASSOCIATES LLP 1047 EL CAMINO REAL SUITE 201 MENLO PARK, CA 94025				
EXAMINER				
DEJONG, ERIC S				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/646,682

Applicant(s)

FERNANDEZ, DENNIS S.

Examiner

ERIC S. DEJONG

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2007 and 15 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-55 is/are pending in the application.
- 4a) Of the above claim(s) 50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-49 and 51-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/888)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED OFFICE ACTION

Applicants responses filed 10/29/2007 and 02/15/2008 are acknowledged.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Election/Restrictions

Applicant's election without traverse of blood vessel as the species of implantation site, metabolite as the species of biological target and activating/deactivating as the species of reconfiguration in the reply filed on 02/15/2008 is acknowledged.

Upon further review of the instant claims and the prior art of record, the First and Second species election requirement (see pages 2-4 of the Restriction requirement mailed 01/29/2008) has been withdrawn by the examiner.

Claim 50 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 02/15/2008.

Claim Rejections - 35 USC § 112

The rejection of claims 40-43 under 35 USC § 112, second paragraph, as being indefinite is withdrawn in view of amendments made to the instant claims, filed 10/29/2007.

Claim Rejections - 35 USC § 101

The rejection of claims 40-43 under 35 USC §101 because the claimed invention is directed to non-statutory subject matter is withdrawn in view of amendments made to the instant claims, filed 10/29/2007.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 36-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Giuffre (US Patent 6,042,548). The rejection of claims 36-43 is maintained from the Office action mailed 08/08/2007. The rejection of claims 44-49 and 51-55 is necessitated by amendments made to the instant claims, filed 10/29/2007.

The instant claims are drawn to an integrated biosensor and simulation system and a method of use. The system comprises a sensor, a simulator, wherein said simulator is reconfigurable by said simulator. The related method of use comprises the

steps of sensing a biological target to generate a signal, simulating using said signal and a model of the biological target to generate a therapeutic or diagnostic output.

Giuffre discloses a method and a system for registering changes in brain and central nervous system activity by using simulation and signals derived from biosensors (e.g., cardiovascular signal) (See Giuffre, Abstract, col. 4, lines 6-17, and claims 1, 5, 7, 8, 12, and 18). Giuffre discloses generating a signal of a biological target by a biosensor (col. 9, lines 26-37), which reads on a sensor, as recited in claims 36 and 40, and the process step of sensing a biological target to generate a signal, as recited in claim 40. Giuffre discloses computer systems for simulation of brain activity using a signal data and a model to estimate brain and central nervous system activity (see Giuffre, col. 4, line 6 through col. 5, line 11), which reads on a simulator, as recited in claims 36 and 40, and the process step of simulating using the signal and a model of the target to generate a therapeutic or diagnostic output, as recited in claim 40. Giuffre discloses embodiments of trained neural net and self-teaching computer systems that act in real-time to incrementally perturb a system and/or change models until data management is optimal (see Giuffre, Fig 3., col. 4, lines 6-60 and col. 6, lines 53-59), which reads on a sensor reconfigurable by a simulator, as recited in claims 36 and 40, and the process step of a simulator reconfiguring a sensor, as recited in claim 40.

Giuffre further teaches the detection of drug infusions and drug and alcohol levels in the blood for use in the disclosed method and a system for registering changes in brain and central nervous system activity (see Giuffre, col. 7, line 44 through col. 8, line 2), which reads on a sensor that senses a food material for consumption by a

biological target, the generation of a second signal therefrom, and the use of said second signal to generate a therapeutic or diagnostic output as recited claims 37 and 41. Giuffre teaches generating an output according to a regulatory condition by the disclosed simulation system (see Giuffre, col. 7, line 44 through col. 8, line 24), as recited in claims 38 and 42. Giuffre discloses coupling using a trained neural net and self-teaching computer systems (a switch) (see Giuffre, Figs. 1-3 and col. 4, lines 6-60), which reads on a sensor coupled to a simulator via a programmable switch as recited in claims 39 and 43.

Giuffre further teaches the use of separate biosensors for the heart and brain (see Giuffre, col. 4, lines 6-38), which reads on the implantation of a biosensor for the heart and brain, as recited in claims 44 and 52, an array of at least two sensors capable of sensing two different biological targets, as recited in claims 45, 46, 49, 53, and 54, and a neural biological target, as recited in claims 47 and 55. Giuffre further teaches that the disclosed method relies upon neurophysiological and cardiovascular monitoring from said biosensors for training a neural network (see Giuffre, col. 3, lines 55-61 and col. 4, lines 6-60). Following the training of a neural network, Giuffre further teaches that only cardiovascular monitoring by heart associated biosensor and the trained neural network are relied upon to estimate the neurophysiological state of a patient (see Giuffre, col. 4, lines 17-38), which reads on the elected species of reconfiguration comprising activating or deactivating at least one biosensor, as recited in claims 48, 49, 51, and 54.

Response to Arguments

Applicant's arguments filed 10/29/2007 have been fully considered but they are not persuasive.

In regards to the rejection of claims under 35 USC 102(b) as being anticipated by Giuffre, applicants argue that Giuffre does not teach "reconfiguring a sensor". Applicants further cite as support preferred embodiments for reconfiguring a sensor as set forth in paragraphs 0224 and 0225 of the instant specification.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is first noted that the elected species of reconfiguring a biosensor is drawn to the activation or deactivation of said biosensor. It is reiterated from the instant rejection that the disclosed method and system of Giuffre expressly teaches the deactivation of brain associated biosensors following the training of a neural network, which explicitly reads on the elected of reconfiguring a biosensor is drawn to the activation or deactivation. Therefore, it is maintained that the instant claims are anticipated by Giuffre.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC S. DEJONG whose telephone number is (571)272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Moran Marjorie can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric S DeJong
Primary Examiner
Art Unit 1631

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